K132667

510(k) SUMMARY

Topcon Medical Systems, Inc.
Synergy ODM

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Topcon Medical Systems, Inc.
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OCT 0 9 2013

OR

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Date Prepared: August 26, 2013

Name of Device and Name/Address of Sponsor

Synergy ODM
Topcon Medical Systems, Inc.
111 Bauer Drive
Oakland, NJ 07436

Common or Usual Name

System, image management, ophthalmic

Classification Name

21 C.F.R. 892.2050

Predicate Devices

Topcon Corporation Synergy (K093313)
Carl Zeiss Meditec AG Forum (K122938)

Intended Use / Indications for Use

Synergy ODM is a comprehensive software platform intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments or through computerized networks.

Technological Characteristics

Synergy ODM is a software platform that collects, processes, measures, analyzes, stores, and manages patient data and clinical information. Synergy ODM is used together with a number of computerized digital imaging devices. In addition, Synergy ODM software collects and manages patient demographics, image data, and clinical reports from a range of medical devices. Synergy ODM enables a real-time review of diagnostic patient information at a PC workstation. Synergy ODM also includes an internet-browser-based user interface to allow authorized users to access, view, create reports, and analyze patient and examination data saved in a centralized database. The system utilizes dual level authentication and 128-bit encryption to ensure secure networking environment.

Performance Data

No performance data was required or provided. Software validation and verification demonstrate that the Synergy ODM performs as intended and meets its' specifications.

Substantial Equivalence

Synergy ODM is as safe and effective as the identified predicate devices including Topcon Corporation's Synergy (K093313) and Zeiss Forum (K122938). Synergy ODM has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. Both Synergy ODM and the predicate devices have similar technological characteristics. Synergy ODM and the identified predicate devices are software only devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 9, 2013

Topcon Medical Systems
c/o Ms. Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K132667
Trade/Device Name: Synergy ODM
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system.
Regulatory Class: Class II
Product Code: NFJ
Dated: August 26, 2013
Received: August 27, 2013

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132667

Device Name: Synergy ODM

Indications for Use:

Synergy ODM is a comprehensive software platform intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments or through computerized networks.

Prescription Use ___X__ Use____ (Part 21 C.F.R. 801 Subpart D) Subpart C)	AND/OR	Over-The-Counter (21 C.F.R. 807

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Rahul K. Ram -S (Affiliate)